



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Laboratory Quality Assurance
1610 NE 150th Street
Shoreline, WA 98155-9701

TO: Medical Test Sites

FROM: Office of Laboratory Quality Assurance

SUBJECT: Application for Licensure

Please complete the enclosed application. The information requested, including the **owner's signature** and the **tax ID number**, must be complete or we will be unable to process your application and issue you a license. **DO NOT SEND ANY MONEY WITH YOUR APPLICATION.** We will send you a bill for your license after review of your application.

Included in this packet are:

- 1) Cover Letter
- 2) Application Form
- 3) Proficiency Testing (PT) Enrollment

The State has received approval of its Medical Test Site (MTS) licensure program from the Centers for Medicare and Medicaid Services (CMS); we are exempt from CLIA. You do not need to apply to CMS for a CLIA number. When your MTS application is processed we will assign you an MTS number and a CLIA number. Both your MTS number and your CLIA number will be printed on your license.

PAGES 1 - 2:

Complete all the information requested; include your federal tax ID number. The person that you list as the contact person will receive all information that we mail to your medical test site. If you have a separate individual and address where you would like your fee statement sent, please indicate on the first page of the application.

ACCREDITED: If you are applying for an "Accredited" license, your MTS **MUST** be inspected by the accreditation organization. In settings such as hospitals, where testing may be performed at different locations, **ALL** areas of laboratory testing must be covered by an MTS license. It is the facility's choice whether or not to include point of care (ancillary) testing under the same MTS license as the main laboratory, or license separately. Please coordinate with administration to ensure that all testing is licensed. Proof of accreditation or certification by the accreditation body must be included with your application.

JCAHO has granted the Washington State MTS licensing program deemed status. If your MTS is located in a facility accredited by JCAHO, you have the option of being inspected by the state Office of Laboratory Quality Assurance. If your medical test site is currently accredited by JCAHO and you choose to have the MTS program do the laboratory inspection, do not put a checkmark in the "Accredited" box on page 2 of the application.

CERTIFICATE OF WAIVER: Place a checkmark by all waived tests performed under your medical test site license.

PPMP: Check these tests if they are **ONLY** performed by one of the providers listed. If other personnel perform these tests, place the checkmarks in the appropriate place on page 5 of the application.

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PAGES 3 - 6: *(complete pages 5-6 only if other than waived or PPMP tests are performed)*

Place a checkmark by all tests that are performed at your facility. Include a yearly estimate of the total volume of all tests for each Specialty/Subspecialty (**bold headings**). When counting test volumes do not include waived tests or the PPMP tests performed by a qualified provider. Count each test included in a panel or a profile as a separate test. **For CBCs, count the measured parameters as separate tests.** Example: RBC, WBC, Hemoglobin, MCV, Platelet Count, and Automated Differential are separate parameters measured by your hematology analyzer; the test count would be 6 separate tests. If manual differentials are performed, count them as additional tests.

PAGES 7 - 8: *(complete only if other than waived or PPMP tests are performed)*

This portion of the application includes the categories of personnel required for moderate and high complexity testing. Place a checkmark by the appropriate personnel qualifications.

FEES:

The information requested in the application will be analyzed to determine the category of license that is required. After we review your application, we will send you a bill for your license fee. **DO NOT SEND A CHECK WITH YOUR APPLICATION.**

The categories are based on the number of specialties (SPEC) performed and the estimated annual volume of testing. The license categories and the **BIENNIAL** fees are:

CATEGORY	FEE	ACCREDITED CATEGORY	FEE
WAIVER	\$ 150		
PPMP	200		
Low Volume (1-2000)	450	Accredited Low Volume	\$ 165
A (2,001-10,000, 3 SPEC)	1,364	Accredited Category A	211
B (2001-10,000, 4 SPEC)	1,769	Accredited Category B	231
C (10,001-25,000, 3 SPEC)	2,454	Accredited Category C	531
D (10,001-25,000, 4 SPEC)	2,818	Accredited Category D	559
E (25,001-50,000)	3,382	Accredited Category E	787
F (50,001-75,000)	4,187	Accredited Category F	1,254
G (75,001-100,000)	4,991	Accredited Category G	1,722
H (100,001-500,000)	5,835	Accredited Category H	2,227
I (500,001-1,000,000)	10,369	Accredited Category I	6,428
J (>1,000,000)	12,443	Accredited Category J	8,168

If you have any questions or need assistance in completing the application form, please contact our Seattle office at (206)361-2802 or our Eastern Washington office at (509)764-6789.

Additional information is available on our website at: www.doh.wa.gov/lqa.htm

NOTE: TO PROCESS THE APPLICATION, WE MUST HAVE THE TAX ID NUMBER (page 1) AND OWNER'S SIGNATURE (page 2) OF THE APPLICATION.

WASHINGTON STATE DEPARTMENT OF HEALTH
OFFICE OF LABORATORY QUALITY ASSURANCE
1610 NE 150TH STREET
SHORELINE, WA 98155-9701
(206) 361-2802

[x] Initial

MEDICAL TEST SITE LICENSE APPLICATION

MTS LICENSE #:

CLIA #:

COMPLETE ALL OF THE INFORMATION LISTED BELOW

FEDERAL TAX ID (EIN) #:

NAME:

(40 characters maximum)

SITE ADDRESS:

MAILING ADDRESS (and billing address, if different):

TELEPHONE #:

FAX #

OWNER:

DIRECTOR:

(include qualifications: i.e., MD, PhD, BS, etc.)

CONTACT PERSON:

E-MAIL ADDRESS:

SITE TYPE (check one only)

- | | | |
|---|--|---|
| <input type="checkbox"/> 1 Ambulatory Surgery Center | <input type="checkbox"/> 10 Hospital | <input type="checkbox"/> 20 Other Practitioner _____ |
| <input type="checkbox"/> 2 Community Clinic | <input type="checkbox"/> 11 Independent Laboratory | <input type="checkbox"/> 21 Tissue Bank/Repositories |
| <input type="checkbox"/> 3 Comp. Outpatient Rehab. Facility | <input type="checkbox"/> 12 Industrial | <input type="checkbox"/> 22 Blood Banks |
| <input type="checkbox"/> 4 Ancillary Testing Site | <input type="checkbox"/> 13 Insurance | <input type="checkbox"/> 23 Rural Health Clinic |
| <input type="checkbox"/> 5 End Stage Renal Disease Facility | <input type="checkbox"/> 14 ICFMR | <input type="checkbox"/> 24 Federally Qualified Health Center |
| <input type="checkbox"/> 6 Health Fair | <input type="checkbox"/> 15 Mobile Unit | <input type="checkbox"/> 25 Ambulance |
| <input type="checkbox"/> 7 Health Main. Organization | <input type="checkbox"/> 16 Pharmacy | <input type="checkbox"/> 26 Health Department |
| <input type="checkbox"/> 8 Home Health Agency | <input type="checkbox"/> 17 Student Health | <input type="checkbox"/> 90 Drug Treatment |
| <input type="checkbox"/> 9 Hospice | <input type="checkbox"/> 18 Skilled Nursing Facility | <input type="checkbox"/> 91 Clinic |
| | <input type="checkbox"/> 19 Physician Office | <input type="checkbox"/> 99 Other _____ |

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MEDICAL TEST SITE LICENSE APPLICATION - page 2

MULTIPLE SITES (list number of sites if you have multiple sites **AND** the paragraph below applies)_____

If you qualify as a **NOT-FOR-PROFIT** laboratory or State or local government laboratory that performs limited public health testing (total of 15 or less waived or moderate complexity tests) at different locations, you may apply for **one** license.

ATTACH a **LIST OF NAMES, ADDRESSES AND MTS LICENSE NUMBERS** (if applicable) for the sites you will be consolidating under one license, and a **LIST OF TESTS PERFORMED AT EACH SITE**. If you are not a state or local government laboratory, you **MUST** include a copy of your federal 501(c)(3) determination letter to be licensed in this manner.

ACCREDITED: (check here only if you are **inspected** and accredited by one of the following)

☐ AABB ☐ AOA ☐ ASHI ☐ CAP ☐ COLA ☐ JCAHO

To qualify for this type of license you **MUST** include proof of accreditation or certification of the laboratory testing at your facility with your application (*See information in accompanying letter regarding accreditation licenses*). If you have not yet been inspected by the accrediting body, include proof of enrollment **with** your application, and forward the proof of accreditation after the survey has been completed.

**If you perform any tests other than the waived or PPMP tests,
complete pages 5-8 of this application.**

READ THE FOLLOWING CAREFULLY BEFORE SIGNING APPLICATION

As listed under RCW 70.42.160, any licensee who has knowingly or with reason to know made a false statement of a material fact in the application for a license or in any data attached thereto or in any record required by the department may be assessed a monetary penalty of up to ten thousand dollars per violation in addition to or in lieu of conditioning, suspending, or revoking a license.

I certify that the information included in this application is accurate and complete.

Signature of Owner/Authorized Representative of Medical Test Site

Date

MEDICAL TEST SITE LICENSE APPLICATION - page 3

CERTIFICATE OF WAIVER: If you perform any of the specific test methods listed below, put a checkmark by the test system/kit that you are using. (waived test list as of 03/10/03)

Alanine Aminotransferase (ALT)

☐ Cholestech LDX Alanine Amino Transferase (ALT)

Bladder tumor associated antigen

☐ Bion Diagnostic Sciences BTA *stat* Test (for home use)
☐ Maritech BladderCheck Test (professional & prescription use)

Catalase, urine

☐ Diatech Diagnostics Uriscreeen (for OTC use)

Cholesterol

☐ Accu-Check InstantPlus Cholesterol test system
☐ Advanced Care Cholesterol measuring system
☐ ChemTrak AccuMeter Cholesterol test system
☐ Cholestech LDX Test System
☐ ENA C.T. Total Cholesterol or Total Cholesterol (PDU)
☐ Lifestream Technologies Cholesterol Monitor
☐ Lifestream Technologist Personal Cholesterol Monitor
☐ Polymer Technology Systems Bioscanner / 2000PST Test Strips
☐ Polymer Technology Systems MTM BioScanner 1000 (OTC)

Creatinine

☐ Bayer Clinitek 50 Urine Chemistry Analyzer for Creatinine
☐ Bayer Diagnostics MICROALBUSTIX Reagent Strips
☐ Bayer MultiStix PRO 11 and PRO 7G

Drugs of Abuse

☐ Advantage Diagnostics THC/COC and combo kit
☐ Alatech Scientific Peace of Mind Multiple Drugs of Abuse
☐ Forefront Diag. DrugFree Home TCH and COC kit
☐ Forefront Diag. Instacheck Multi-Drug Screen (THC/COC)
☐ Phamatec At Home & QuickScreen (At Home (OTC), One Step, Pro MultiDrug) Drug Tests
☐ Princeton Biomeditech Drug Tests
☐ Worldwide Medical Corp. First Check Home Drug Tests

Erythrocyte sedimentation rate (ESR)

☐ Non-automated

Ethanol

☐ OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test
☐ OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test

Fern Test

☐ TCI Ovulation Tester (Fern test, Saliva)

Follicle Stimulating Hormone (FSH)

☐ Genua Menopause Monitor Test, FSH (qualitative)

Fructosamine

☐ LXN (Duet and IN CHARGE Test Systems)

Glucose

☐ Blood glucose monitoring devices cleared by the FDA for home use
☐ Cygnus, Inc GlucoWatch Automatic Glucose Biographer
☐ Hemocue B-Glucose Photometer & model 201 analyzer
☐ LXN Duet Glucose Monitoring System fructosamine/glucose
☐ Cholestech LDX

Glycosylated HGB Total yearly volume: _____

☐ Ames DCA 2000 for glycosylated hemoglobin (HgbA1C)
☐ Bayer DCA 2000 for glycosylated hemoglobin (HgbA1C)
☐ Bayer DCA 2000+ for glycosylated hemoglobin (HgbA1C)
☐ Cholestech GDx A1C (prescription home use)
☐ Metrika A1c Now (professional & prescription use models)
☐ Metrika Inc DRx HbA1c for glycated hemoglobin (prescription and professional use models)
☐ Provalis Diagnostics Glycosal HbA1c-glycosylated hemoglobin

HDL Cholesterol

☐ Cholestech LDX
☐ Polymer Technology Systems BioScanner (for OTC use)

Helicobacter Pylori

☐ Abbott FlexPack HP test (whole blood)
☐ Abbott TestPack Plus (whole blood)
☐ Applied Biotech SureStep (whole blood)
☐ Ballard (Delta West) CLOtest (gastric biopsy)
☐ Beckman Coulter Flexsure (whole blood)
☐ Becton Dickinson LINK 2 (whole blood)
☐ ChemTrak AccuMeter (whole blood)
☐ GI Supply HP-FAST (gastric biopsy tissue)
☐ JANT Pharmacal Corp. *H. pylori* Test
☐ LifeSign *H. pylori* WB (whole blood)
☐ LifeSign Status *H. pylori* (whole blood)
☐ Medical Instruments Corporation Pronto Dry *H. pylori*
☐ Meridian Bioscience ImmunoCare STAT! *H.pylori* (WB)
☐ Polymedco, Inc. Poly stat *H. pylori* (whole blood)
☐ Princeton BioMeditech BioSign *H. pylori* WB
☐ Quidel QuickVue One-Step (whole blood)
☐ Quidel QuickVue One-Step *H. pylori* II (whole blood)
☐ REMEL RIM A.R.C. *H. pylori* Test
☐ Roche/BMC AccuStat *H. pylori* OneStep (whole blood)
☐ Serim Pyloritek Test Kit (gastric biopsy tissue)
☐ Serim Pyloritek VP Test Kit
☐ SmithKline FlexSure HP (whole blood)
☐ Trinity Uni-Gold *H. pylori* (whole blood)

Hematocrit

☐ Microhematocrit (spun)
☐ Wampole STAT-CRIT for hematocrit
☐ Micro Diagnostics Spuncrit DRC-40 Infrared Analyzer

Hemoglobin

☐ Copper Sulfate (non-automated)
☐ HemoCue hemoglobin (automated) by single analyte instruments with self-contained or component features to perform specimen-reagent interaction, providing direct measurement and readout
☐ GDS Diagnostics HemoSite Meter for hemoglobin
☐ GDS Technology STAT-Site MHgb Test System

HIV-1

☐ OraQuick Rapid HIV-1 Antibody Test (fingerstick whole blood)

Influenza

☐ Quidel QuickVue Influenza Test (Influenza A/B)
☐ ZymeTX Zstatflu (Influenza A/B)

Ketones

☐ Abbott Laboratories, Medisens Products Precision Xtra
☐ Advanced Diabetes Management System [ketones]
☐ Polymer Technology Systems BioScanner (for OTC use)

Lactic Acid

☐ KDK Corporation Lactate Pro System (for OTC use)

Lipid Profile (Cholesterol, HDL Cholesterol and Triglycerides)

☐ Cholestech LDX
☐ Polymer Technology Systems Bioscanner PLES, Cardiocheck, Cardiocheck PA

Lyme Disease

☐ Wampole PreVue *B. burgdorferi* Antibody

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MEDICAL TEST SITE LICENSE APPLICATION - page 4

(Additional waived tests)

Microalbumin

- ☐ Roche/Boehringer Mannheim Micral Chemstrip
- ☐ Bayer Clinitek 50 Urine Chemistry Analyzer
- ☐ Bayer Diagnostics MICROALBUSTIX Reagent Strips
- ☐ Diagnostic Chemicals ImmunoDip Urinary Albumin
- ☐ Diagnostic Chemicals Urinary Albumin Screen (microalbumin)

Mononucleosis

- ☐ Applied Biotech, Inc. SureStep Mono Test (whole blood)
- ☐ BioStar Aceava Mono Test (whole blood)
- ☐ Genzyme Diagnostic Contrast Mono (whole blood)
- ☐ Jant Accutest Infectious Mononucleosis Test (whole blood)
- ☐ LifeSign UniStep Mono Test (whole blood)
- ☐ Meridian ImmunoCard STAT Mono (whole blood)
- ☐ Polymedco, Inc. Poly stat Mono (whole blood)
- ☐ Princeton BioMeditech BioSign Mono WB (whole blood)
- ☐ Quidel CARDS O.S. Mono (whole blood)
- ☐ Quidel QuickVue+ Infectious Mononucleosis (whole blood)
- ☐ Remel RIM A.R.C. Mono Test (whole blood)
- ☐ Seradyn Color Q Mono (whole blood)
- ☐ Wampole Mono-Plus WB (whole blood)
- ☐ Wyntek Diagnostics OSOM Mono test (whole blood)
- ☐ Wyntek Diagnostics Signify Mono Test (whole blood)

Nicotine (or its metabolites)

- ☐ DynaGen NicCheck 1 Test Strips

Occult blood

- ☐ Fecal Occult Blood
- ☐ Beckman Coulter Primary Care Diagnostics Gastroccult
- ☐ Smithkline Gastroccult

Osteoporosis

- ☐ Ostex International Osteomark NTX

Ovulation Tests

- ☐ Visual color comparison tests for human luteinizing hormone

PH

- ☐ All qual. color comparison pH testing of body fluids (not blood)
- ☐ Litmus Concepts FemExam Test Card (vaginal pH & amines)

Pregnancy Test (Urine)

- ☐ Urine pregnancy test: visual color comparison
- ☐ Bayer Clinitek 50 Urine Chemistry Analyzer

Protine

- ☐ AvoSure Pro (professional use)
- ☐ AvoSure PT (prescription home use)
- ☐ International Technidyne Corporation Protine Microcoagulation System and ProTime 3 Cuvette System
- ☐ Lifescan Harmony INR Monitoring System
- ☐ Lifescan Rubicom Prothrombin Time Monitoring System
- ☐ Roche/BMC CoaguChek (PST and professional use models)
- ☐ Roche Diag. CoaguChek S Systems (professional use)
- ☐ Roche Diag CoaguChek & CoaguChek S Systems, PT-S Strips

Semen

- ☐ Embryotech Laboratories FertilMARQ for male infertility

Strep Antigen Test

- ☐ Abbott Signify Strep A Test
- ☐ Acon Strep A Rapid Strip Test
- ☐ Applied Biotech SureStep Strep A (II) (direct throat swab)
- ☐ Beckman Coulter Primary Care Diagnostics ICON DS Strep A
- ☐ Beckman Coulter Primary Care Diagnostics ICON FX Strep A
- ☐ Becton Dickinson LINK 2 Strep A Rapid test (throat swab)
- ☐ Binax NOW Strep A Test
- ☐ BioStar AceavaTM Strep A Test
- ☐ DE Healthcare Products, TruView Strep A Test
- ☐ Fisher HealthCare Sure-View Strep A (direct throat swab)
- ☐ Genzyme Contrast Strep A (direct throat swab)
- ☐ Genzyme OSOM Strep A Ultra Test (25 test kit size)
- ☐ Germaine Laboratories StrepAim Rapid Dipstick Test
- ☐ Henry Schein Inc, One Step+ Strep A Test
- ☐ Jant Pharmacal AccuStrip Strep A (II) (direct throat swab)
- ☐ LifeSign LLC Stratus Strep A
- ☐ Mainline Confirms Strep A Dots test (direct throat swab)
- ☐ Meridian Diag. ImmunoCard STAT Strep A (throat swab)
- ☐ Polymedco, Inc. Poly stat A (II) (Group A Strep)(throat swab)
- ☐ Princeton BioMediTech BioStrep A Test
- ☐ Quidel QuickVue In-Line Strep A Test
- ☐ Quidel QuickVue Dipstick Strep A
- ☐ Remel RIM A.R.C. Strep A Test (direct from throat swab)
- ☐ SmithKline ICON Fx (throat swab only)
- ☐ Wyntek Diagnostics OSOM Strep A Test
- ☐ Wyntek Diagnostics OSOM Ultra Strep A Test

Triglycerides

- ☐ Cholestech LDX
- ☐ Polymer Technology Systems, Inc., BioScanner 2000 and BioScanner 2000PTS Panel Test strips

Urinalysis

- ☐ Urinalysis: Dipstick or tablet reagent (**nonautomated**)
- ☐ Bayer Clinitek 50 Urine Chemistry Analyzer
- ☐ Hypoguard Diascreen 50 Urine Chemistry Analyzer
- ☐ Roche/BMC Mini UA (instrument for urinalysis)
- ☐ Roche/BMC Chemstrip 101 Urine Analyzer
- ☐ Teco Diagnostics URITEK TC-101 Urine Strip Reader
- ☐ ThermoBiostar PocketChem UA

PROVIDER-PERFORMED MICROSCOPIC PROCEDURES (PPMP): Check tests listed below if these tests are **only performed** in your office by an MD, DO, DPM, ARNP, Nurse Midwife, PA, Naturopath, or Dentist. If these tests are performed by other personnel in your office, fill out **page 5** of the application.

- ☐ Direct wet mount preparations for the presence or absence of bacteria, fungi, parasites, and human cellular elements
- ☐ Fecal leukocyte examinations
- ☐ Fern tests
- ☐ Nasal Smears for granulocytes
- ☐ Pinworm examinations

- ☐ Post-coital direct, qualitative examinations of vaginal or cervical mucous
- ☐ Potassium hydroxide (KOH) preparations
- ☐ Qualitative semen analysis (limited to the presence/absence of sperm and detection of motility)
- ☐ Urine sediment examinations

MEDICAL TEST SITE LICENSE APPLICATION - page 5

Complete this part only if you perform non-waived tests or personnel other than MD, DO, DPM, ARNP, PA, Midwife, Naturopath, or Dentist perform PPMP tests.

Place a checkmark by all the nonwaived tests listed that are performed at your medical test site. If the tests that you perform are not specifically listed on the checklist, list them under the appropriate specialty/subspecialty. For volumes include the **YEARLY** estimate of the number of tests performed. **Attach additional sheets if needed.**

TOTAL VOLUME

TOTAL VOLUME

MICROSCOPIC PROCEDURES

(Do not check here if only done by the provider, i.e PPMP)

- ☐ Wet Mounts
- ☐ Fecal Leukocytes
- ☐ KOH
- ☐ Pinworm
- ☐ Post Coital Vaginal Mucous Exam
- ☐ Fern Tests
- ☐ Qualitative Semen Analysis (post vas)
- ☐ Quantitative Semen Analysis
- ☐ Urine Sediment
- ☐ Nasal Smear for Granulocytes

HISTOCOMPATIBILITY

- ☐ Transplant
- ☐ Nontransplant
- (list specific tests)

BACTERIOLOGY

- ☐ AFFIRM VP (TV, GV, YST)
- ☐ Antibiotic Sensitivities
- ☐ Bacterial Antigens
 - ☐ Clostridium difficile
 - ☐ Group A Strep (Rapid test - nonwaived kit)
 - ☐ Group B Strep
- ☐ Chlamydia
- ☐ Gram Stain
- ☐ GC
- ☐ Throat Culture
- ☐ Urine Culture
- ☐ Urine Colony Count
- ☐ Other Culture/ID

MYCOBACTERIOLOGY

- ☐ AFB Smear Only
- ☐ AFB Smear/Culture
- ☐ AFB Antibiotic Sensitivities
- ☐ AFB Culture & ID

MYCOLOGY

- ☐ DTM only
- ☐ Culture (Growth/No Growth)
 - ☐ Fungus
 - ☐ Yeast
- ☐ Culture and ID
 - ☐ Fungus
 - ☐ Yeast

PARASITOLOGY

- ☐ Direct smear
- ☐ Concentrate/Stain
- ☐ Parasitic Antigens

VIROLOGY

- ☐ Herpes Antigen
- ☐ Herpes Culture
- ☐ Other Viral Cultures
- ☐ Viral Antigen Detection
 - ☐ Influenza
 - ☐ RSV
- ☐ Viral Antibody Detection

SYPHILIS SEROLOGY

- ☐ RPR
- ☐ VDRL
- ☐ MHA-TP (TP-PA)
- ☐ FTA

GEN. IMMUNOLOGY

- ☐ Allergy Testing
- ☐ Alpha-1 Antitrypsin
- ☐ AFP/Tumor
 - ☐ AFP/Other
- ☐ ANA
- ☐ ASO
- ☐ HIV
- ☐ C3
- ☐ C4
- ☐ HBsAg
- ☐ Anti-HBc
- ☐ HBeAg
- ☐ IgA
- ☐ IgG
- ☐ IgE
- ☐ IgM
- ☐ Infectious Mononucleosis - nonwaived kits
- ☐ Rheumatoid Factor
- ☐ H. pylori (nonwaived methods)
- ☐ Rubella Antibody
- ☐ Protein Electrophoresis
- ☐ Other (list)

ROUTINE CHEMISTRY

- ☐ ALT/SGPT
- ☐ Albumin
- ☐ Alkaline Phosphatase
- ☐ Amylase
- ☐ AST/SGOT
- ☐ Bilirubin, Total/Neonatal
- ☐ pH (blood gas)
- ☐ pO₂ (blood gas)
- ☐ pCO₂ (blood gas)
- ☐ Calcium, Total
- ☐ Carbon Dioxide
- ☐ Chloride

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MEDICAL TEST SITE LICENSE APPLICATION - page 7

PERSONNEL QUALIFICATION REQUIREMENTS

Complete this form if:

- 1) Your medical test site performs any tests other than the waived tests listed in pages 3-4 of the application;
- 2) Personnel **OTHER** than MD, DO, DPM, ARNP, PA, Midwife, Naturopath, or Dentist perform the tests listed under PPMP on page 4 of the application.

MODERATE COMPLEXITY TESTING

Director (check only one)

- ☐ 1. Pathologist w/State license
- ☐ 2. MD, DO, DPM w/State license
 - + 1 yr directing or supervising non-waived testing; or
 - 20 CMEs in laboratory practice; or
 - lab training during residency equivalent to 20 CMEs
- ☐ 3. PhD in science
 - + board certification (ABB, ABMM, ABCC, ABMLI); or
 - 1 yr directing or supervising non-waived testing
- ☐ 4. Master in science
 - + 1 yr lab training and/or experience; and
 - 1 yr laboratory supervisory experience
- ☐ 5. Bachelor in science
 - + 2 yrs lab training and/or experience; and
 - 2 yrs laboratory supervisory experience
- ☐ 6. On 2/28/92, serving as a lab director and qualified or could have qualified as director under previous Medicare/CLIA independent lab personnel requirements
- ☐ 7. On 2/28/92, was qualified under State law to direct lab

Clinical Consultant (check only one)

- ☐ 1. Pathologist w/State license
- ☐ 2. MD, DO, DPM w/State license
- ☐ 3. PhD in science
 - + board certification (ABB, ABMM, ABCC, ABMLI)

Technical Consultant (include total # of personnel performing duties in front of appropriate categories)

- ☐ 1. Pathologist w/State license
- ☐ 2. MD, DO, DPM w/State license
 - + 1 yr training and/or exper. in the laboratory specialty
- ☐ 3. PhD or Master in science
 - + 1 yr training and/or exper. in the laboratory specialty
- ☐ 4. Bachelor in science
 - + 2 yr training and/or exper. in the laboratory specialty
- ☐ 5. On 2/28/92, serving as a lab director and qualified or could have qualified as director under previous Medicare/CLIA independent lab personnel requirements

Testing Personnel (include total # of personnel performing testing in front of appropriate categories)

- ☐ 1. MD, DO, DPM, PhD, master or bachelor degree in science, or associate degree in science or medical lab technology
- ☐ 2. H.S. graduate or equivalent
 - + 50 week military medical laboratory procedures course
- ☐ 3. H.S. graduate or equivalent with documented training for testing performed

HIGH COMPLEXITY TESTING

Director (check only one)

- ☐ 1. Pathologist w/ State license
- ☐ 2. MD, DO, DPM w/State license
 - + 1 yr lab training during medical residency; or
 - 2 yrs directing or supervising high complexity testing
- ☐ 3. PhD in science
 - + board certification (ABB, ABMM, ABCC, ABMLI); or
 - Until 12/31/2002: 2 yrs lab training and/or experience and
 - 2 yrs directing or supervising high complexity testing
- ☐ 4. On 2/28/92, serving as a lab director and qualified or could have qualified as director under previous Medicare/CLIA independent lab personnel requirements
- ☐ 5. On 2/28/92, was qualified under State law to direct lab
- ☐ 6. For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology (dentists), American Board of Pathology, or American Osteopathic Board of Pathology or equivalent

Clinical Consultant (check only one)

- ☐ 1. Pathologist w/State license
- ☐ 2. MD, DO, DPM w/State license
- ☐ 3. PhD in science
 - + board certification (ABB, ABMM, ABCC, ABMLI)
- ☐ 4. DDS certified in oral pathology (ABOP, ABP, AOBP)

Technical Supervisor Qualifications:

Chemistry, Hematology, Bacteriology, Mycology, Mycobacteriology, Parasitology, Virology and Diagnostic Immunology

(include total # of personnel performing duties in front of appropriate categories)

- ☐ 1. Pathologist w/State license
- ☐ 2. MD, DO, DPM w/State license
 - + 1 yr training and/or experience in high complexity testing in laboratory specialty
- ☐ 3. PhD in science
 - + 1 yr training and/or experience in high complexity testing in laboratory specialty
- ☐ 4. Master in science
 - + 2 yrs training and/or experience in high complexity testing in laboratory specialty
- ☐ 5. Bachelor in science
 - + 4 yrs training and/or experience in high complexity testing in laboratory specialty
- ☐ 6. On 2/28/92, serving as a lab director and qualified or could have qualified as director under previous Medicare/CLIA independent lab personnel requirements

PERSONNEL QUALIFICATION REQUIREMENTS (continued)

HIGH COMPLEXITY TESTING (continued)

Technical Supervisor Qualifications:

Histocompatibility, Cytogenetics,

Immunohematology and Pathology

Histocompatibility

- ____ 1. MD, DO, DPM w/State license or PhD
+ 4 yrs of training and/or experience in histocompatibility;
or 2 yr in general immunology + 2 yr in histocompatibility

Cytogenetics

- ____ 1. MD, DO, DPM w/State license or PhD
+ 4 yrs of training and/or experience in genetics, 2 of which
have been in clinical cytogenetics

Immunohematology

- ____ 1. Pathologist w/State license
____ 2. MD, DO, DPM w/State license
+ 1 yr of training and/or experience in high complexity
immunohematology

Pathology

- ____ 1. For histopathology, anatomic pathologist;*
____ 2. For dermatopathology, anatomic pathologist,
dermatopathologist, or dermatologist certified by American
Board of dermatology*
____ 3. For oral pathology, anatomic pathologist or oral path.*
____ 4. For ophthalmic pathology, anatomic pathologist or certified by
American Board of Ophthalmology*
____ 5. For cytology, anatomic pathologist or MD/DO certified by
American Society of Cytology**

* Can delegate responsibility for examination and interpretation to a resident

** Can delegate some responsibilities to resident in final year of full-time
training

**General Supervisor (include total # of personnel performing
duties in front of appropriate categories)**

- ____ 1. Pathologist w/State license
____ 2. MD, DO, DPM w/State license + 1 yr of training and/or
experience in high complexity testing
____ 3. PhD, master or bachelor in science
+ 1 yr training and/or exper. in high complexity testing
____ 4. AS/AA in lab science or medical technology + 2 yr
training and/or exper. in high complexity testing
____ 5. Education equivalent to AA degree (60 semester hrs) in lab
science + documented lab training program (at least 3 mos);
+ 2 yr T/or E in high complex. testing
____ 6. On 2/28/92, qualified or could have qualified under previous
Medicare/CLIA independent lab personnel requirements.
____ 7. On 9/1/92 served as gen supv + on 4/24/95 graduated from
med lab clinical training program or 50 week US
military pgm + have 2 yrs T/or E in high complex. testing
____ 8. On 9/1/92 served as G.S. + high school graduate + 10 years
T&E in high complex. testing, including 6 yrs
supervisory between 9/1/82-9/1/92.

**General supervisor: Blood Gas Analysis (include total # of
personnel performing duties in front of appropriate categories)**

- ____ 1. Qualify as a general supervisor of high complexity testing
listed above
____ 2. Bachelor degree in respiratory therapy or cardiovascular
technology + 1 yr training and/or exper. in blood gases
____ 3. Associate degree related to pulmonary function
+ 2 yrs training and/or experience in blood gas analysis

**Testing Personnel (include total # of personnel performing testing
in front of appropriate categories)**

- ____ 1. MD, DO, DPM w/State license, PhD, master, bachelor or
associate degree in science
____ 2. 60 semester hrs in science + approved lab training pgm
____ 3. On 2/28/92, previously qualified or could have qualified as
a technologist under previous Medicare/CLIA
independent lab personnel requirements
____ 4. On 4/24/95, H.S. graduate performing high complexity testing
+ completed med lab clinical training program or
50 week US military pgm
____ 5. On 4/24/95, H.S. graduate performing high complexity
testing + appropriate training
____ 6. Until 9/1/97, H.S. graduate or equivalent with documented
training for the testing performed (if hired before 1/19/93,
no direct on-site supervision if results reviewed by
general supervisor within 24 hours)
____ 7. For blood gas analysis, qualify under 1, 2, 3, 4, 5, 6;
or bachelor in resp. therapy or cardiovascular technology;
or associate degree in pulmonary function

Cytology General Supervisor

- ____ 1. Qualify as a technical supervisor in cytology
____ 2. Qualify as a cytotechnologist + 3 yrs full time
(2080 hrs/yr) experience within preceding 10 yrs

**Cytotechnologist (include total # of personnel performing testing
in front of appropriate categories)**

- ____ 1. Anatomic pathologist or cytopathologist or resident
____ 2. Graduate from an accredited school of cytotechnology
____ 3. Certified in cytotechnology by an approved agency
____ 4. Prior to 9/1/92:
• 2 yrs of college (12 semester hrs in science, 8 of which
are biology, + 12 mos training in an approved school of
cytotechnology; or
• 6 mos of formal training in an approved school of
cytotechnology + 6 mos FT experience in cytotechnology
in lab acceptable to pathologist who directed training; or
• achieved a satisfactory grade in an HHS proficiency
exam for cytotechnologist
____ 5. Prior to 9/1/94:
• 2 yrs FT exp. within preceding 5 yrs examining slide
preps under supervision of a TS in cytology; and
Prior to 1/1/69:
• graduated from high school; and
• completed 6 mos training in cytotechnology directed by
a pathologist or other MD providing cytology services; and
• 2 yrs FT supervised experience in cytotechnology
____ 6. Prior to 9/1/94:
• 2 yrs of FT experience under supervision of a TS in cytology
in US in past 5 yrs; and by 9/1/95 graduate from an accredited
school or be certified by an approved agency

Proficiency Testing

(not applicable for Waived or PPMP licenses)

Proficiency testing (PT), as required under Medical Test Site rule 246-338-050, is a source of external quality control. This practice of testing unknown specimens from an outside source provides an additional means to assure quality laboratory testing results. Although laboratories perform daily internal quality control with their test systems, external quality control provides important interlaboratory comparisons to determine the accuracy and reliability of your testing procedures.

You must enroll in PT for all regulated analytes listed on the next page. A listing of the currently approved PT programs and their phone numbers can also be found on the back page. Call the programs for a free copy of their PT brochure.

You must enroll in programs that cover the testing that you are performing. Generally, most programs are five sample modules shipped in three test events during the year. All **regulated analytes** must be covered by PT under the five sample program.

Information needed to enroll: Complete the Order Form in the PT brochure which asks for your name (use the NAME **exactly** as it appears on your MTS license, no other name accepted), address, CLIA ID Number and your MTS license number, and select the appropriate program for your laboratory. Remember to indicate on the order form that a copy of your PT results be sent to the Office of Laboratory Quality Assurance; **this must be done for each analyte!**

For PPMP procedures and moderate and high complexity tests that are not on the regulated analyte list, you must have a means of establishing the accuracy of the procedure two times a year (biannual verification). The two sample PT programs can be used for this purpose for tests that are not included on the regulated analyte list.

What must I do if I add a new test? You must notify our office within 30 days and if this new test is a regulated analyte, you must cover the test in the next PT event. When you notify us, we will remind you to enroll in PT and ask you for proof of enrollment.

What if I decide to stop testing an analyte? You must notify our office within 30 days that you have stopped testing. If you have signed up for PT for this analyte, be sure to choose the code “test not performed” on the PT answer sheet.

If you have other questions, contact Leonard Kargacin at (206) 361-2804, or Gary Utter at (509) 764-6789.

Additional information is available at our website: <http://www.doh.wa.gov/LQA.htm>.

TIPS for Proficiency Testing Success
Improve your chances for successful participation in PT, by considering the following suggestions:

- ✍ **Fill in the Method Code**
Remember to always fill in the method code, do not leave blank
- ✍ **Correctly report the reason PT was not done**
If you are unable to test for some reason, be certain to indicate this on the answer sheet. If you discontinued testing for an analyte, indicate this on the sheet. Immediately notify LQA of any change.
- ✍ **Be timely**
Always be sure to meet the deadline for returning your results.
- ✍ **Review your graded results**

Approved Proficiency Testing Providers

Accutest (800) 356-6788
 Amer. Acad. of Family Physicians (800) 274-7911
 Amer. Assoc. of Bioanalysts (800) 234-5315
 American Proficiency Institute (800) 333-0958
 ASIM Medical Lab Evaluation (800) 338-2746

California Thoracic Society (714) 730-1944
 College of American Pathologists (800) 323-4040
 EXCEL (CAP) (800) 323-4040
 Idaho Bureau of Laboratories (208) 334-2235
 Wisconsin State Lab. of Hygiene (800) 462-5261

REGULATED ANALYTES: These Tests MUST Be Covered By PT

CHEMISTRY

ALT/SGPT
 Albumin
 Alkaline phosphatase
 Amylase
 AST/SGOT
 Bilirubin, total (or neonat.)
 Blood gas pO₂, pCO₂, pH
 Calcium, total
 Chloride
 Cholesterol, total
 HDL cholesterol
 Creatine kinase
 Creatine kinase isoenzymes
 Creatinine
 Glucose
 Iron, total
 LDH
 LDH isoenzymes
 Magnesium
 Potassium
 Sodium
 Total protein
 Triglycerides
 Urea nitrogen
 Uric acid

ENDOCRINOLOGY

Cortisol
 Free thyroxine
 Serum pregnancy (HCG)
 (qualitative or quantitative)
 T₃ uptake

Triiodothyronine
 TSH

Thyroxine

TOXICOLOGY

Alcohol, blood
 Blood lead
 Carbamazepine
 Digoxin
 Ethosuximide
 Gentamicin
 Lithium
 Phenobarbital
 Phenytoin
 Primidone
 Procainamide (& metabolite)
 Quinidine
 Tobramycin
 Theophylline
 Valproic acid

HEMATOLOGY

Cell identification
 Auto or manual WBC diff.
 Erythrocyte count (RBC)
 Hematocrit (automated)
 Hemoglobin
 Leukocyte count (WBC)
 Platelet count
 Fibrinogen
 Partial thromboplastin time
 Prothrombin time

IMMUNOHEMATOLOGY

ABO group
 D (Rh typing)
 Antibody detection
 Compatibility testing
 Antibody identification
SYPHILIS SEROLOGY
 RPR, VDRL, MHA-TP, etc.

IMMUNOLOGY

Alpha-1 antitrypsin
 AFP (tumor marker)
 Antinuclear antibody
 ASO
 HIV
 Complement C3, C4

IMMUNOLOGY (cont.)

HBsAg, Anti-HBc, HBeAg
 IgA, IgE, IgG, IgM
 Infectious mononucleosis
 Rheumatoid factor
 Rubella

BACTERIOLOGY

Chlamydia
 Direct Strep test
 GC
 Throat culture
 Urine culture ID
 Gram stain
 Other culture/combinations
 Antimicrobial tests

MYCOLOGY

Yeast ID/culture
 Fungus culture - systemic

PARASITOLOGY

Direct only
 Concentration/Stain

VIROLOGY

HSV EIA
 Culture or FA
 Other EIA for virus

MYCOBACTERIOLOGY

AFB Smear and/or culture